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REVIEW ARTICLE

Clinical heterogeneity was a common problem in Cochrane reviews of physiotherapy and occupational therapy

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Abstract

Background and Objective: To identify the strategies used to deal with the clinical heterogeneity of interventions and multiple outcome measures used in Cochrane reviews on physiotherapy and occupational therapy.

Methods: A search for systematic reviews on physiotherapy and occupational therapy in the Cochrane Library was performed. Data on the method of categorization of interventions, on measures, and on the method of data synthesis were systematically extracted.

Results: 52 reviews were identified. In 22 (42%) reviews only one index intervention was evaluated, in the other 30 reviews index interventions were categorized. A large diversity in the number and type of outcome measures was found (median 6.5, range 1–23). In 48% of the reviews one or more primary outcome measures were defined. In 52% of the reviews no quantitative data synthesis was performed, whereas five different methods for qualitative data synthesis were applied in 11 reviews.

Conclusions: Limitation to a few outcome measures and explicit procedures for the categorization of interventions might increase the transparency and reproducibility of systematic reviews on physiotherapy and occupational therapy. Qualitative data synthesis is not often applied, although it is a useful tool to summarize results if a quantitative synthesis is not appropriate. International consensus on a method for qualitative synthesis is clearly needed. © 2006 Elsevier Inc. All rights reserved.

Keywords: Evidence-based medicine; Heterogeneity; Meta-analysis; Occupational therapy; Physiotherapy; Review

1. Introduction

Systematic reviews and meta-analyses are generally accepted to represent the highest level of evidence, and are the cornerstone of evidence-based medicine. Most systematic reviews focus on straightforward interventions such as medication. However, the interventions of allied health care professionals such as physical therapists and occupational therapists are complex and diverse, which complicates research on the efficacy of these interventions.

Physiotherapists and occupational therapists aim to restore functional ability rather than to cure disease. In daily practice, many patients simultaneously suffer from several problems of functioning and disability as defined by the International Classification of Functioning, Disability and Health (ICF) [1], which necessitates the tailoring of therapy

to the patient's abilities and limitations. This means that treatment for a given problem may vary among patients in terms of number of treatment sessions, required, the intensity of treatment, outcomes, etc. Indeed, multiple outcomes are common to such interventions [2–5] that stress the need to label a limited number of outcome measures as “primary.” This diversity of interventions (or clinical heterogeneity) and the use of multiple outcome measures have consequences for the methodology of systematic reviews and reduce the likelihood that clear conclusions can be drawn.

The aim of the present study was to identify the strategies Cochrane reviewers use to deal with clinical heterogeneity of interventions and outcome measures when reviewing the efficacy of physiotherapy and occupational therapy.

2. Methods

We searched for systematic reviews produced by the Cochrane Collaboration on the efficacy of physiotherapy or

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occupational therapy. The Cochrane Database of Systematic Reviews was accessed via PubMed. The following key words were used (April 2004): (“physical therapy” OR physiotherapy OR exercise OR “occupational therapy”) AND (Cochrane Database Syst Rev). Two reviewers (C.H.M.E., E.M.J.S.) independently made the first selection of review articles, based on the titles and abstracts of articles. (A full listing of the characteristics included in the reviews is presented in Table 1a, available at www.elsevier.com). When in doubt, they read the full review. Disagreement was resolved by discussion. No inclusion criteria other than those mentioned in the search strategy were applied. Excluded were

- 1) Reviews evaluating the efficacy of a drug intervention, surgical intervention, or other invasive intervention;
- 2) Reviews of studies in which the setting of treatment was part of the contrast between experimental and control group (i.e., inpatient vs. outpatient treatment);
- 3) Reviews of studies in which a mechanical intervention (such as a device as continuous passive motion device or ultrasound) was part of the experimental intervention.

2.1. Data extraction

Data were retrieved by the same two reviewers, using a standardized form. Agreement on data extraction between the two reviewers was established for a sample of five reviews.

2.2. Clinical heterogeneity in interventions

The number of interventions and the use of a method to distinguish between interventions were regarded as indicators of clinical heterogeneity. Therefore, the number of index interventions (defined as the experimental intervention of primary interest, the effect of which is compared with that of the control intervention) per review was counted. In addition, we recorded whether or not reviewers named explicit criteria and/or a consensus procedure to categorize index interventions in the methods section of the review.

2.3. Information on outcome measures

The number and type of outcome measures were considered indicators of clinical heterogeneity. The number of dimensions Cochrane reviewers used to list the outcome measures in the method section of their reviews was counted. Furthermore, the number of outcome measures reviewers explicitly stated in their review as “primary” was counted and classified into one of three levels of the ICF classification (body functions, activities, and participation [1]).

2.4. Information on the method of data synthesis

The method (qualitative or quantitative) the Cochrane reviewers used for data synthesis was recorded. A data synthesis was considered “quantitative” if a statistical

combination of results from two or more separate studies was performed, and “qualitative” (or “level of evidence synthesis”) if explicit decision rules were applied to formulate conclusions. Reasons for not conducting quantitative data synthesis were recorded. If applicable, the content of the qualitative data synthesis was investigated.

3. Results

The search strategy yielded 189 reviews. If several versions of the same review were available, only the most recent version was considered for inclusion; 32 reviews were excluded. Another 105 reviews were excluded for the following reasons: the review evaluated a drug or invasive intervention (58 reviews); setting of treatment was the main contrast between index and control intervention (2 reviews); and/or a mechanical intervention was part of the index intervention (55 reviews). Fifty-two systematic reviews were included [6–57]; these reviews covered a median of 10 studies (range 0 to 66).

3.1. Interventions

In 22 (42%) reviews only one index intervention was evaluated. In 11 reviews criteria were used to categorize the interventions, and in 3 reviews a consensus procedure was used to categorize the interventions. (for further information: www.elsevier.com). The median number of categories of index intervention per review was two (range 1–16); the median number of included studies per index intervention category was 4.8 (range 0–39).

3.2. Outcome measures

Several outcome dimensions were used in addition to the three dimensions of the ICF, for example “adverse effects,” “economic evaluation,” “measures of physical examination,” and “medication.” The median number of outcomes per review was 6.5 (range 1–23). In many reviews outcomes such as “functional ability” or “pain” were not restricted to specific instruments, which meant that a large number of instruments were investigated.

In 25 (48%) of the reviews one or more *primary* outcome measures were defined in the Method section. The number of primary outcomes varied from 1 to 11 (see Table 1). Level of activities and participation, according to the ICF classification, was the most frequently used primary outcome measure, being used in 18 (34%) of all reviews.

3.3. Data synthesis

In 27 (52%) of the reviews no quantitative data synthesis was performed, and in 17 (33%) reviews neither quantitative nor qualitative synthesis was performed (for further information: www.elsevier.com). The reasons for not conducting a quantitative data synthesis were clinical and/or statistical heterogeneity in 20 reviews [10,13,17,18,21,25,27,29,31,

Table 1

Frequency of primary outcome measures selected in 25 reviews of physical therapy and occupational therapy^a

	N
Functional ability/disability/independence	13
Pain	9
Global improvement	6
Return to work/social participation	6
Quality of life	5
Walking ability	2
Fatigue	2
Exercise tolerance	2
Death	2
Other (mentioned in one review)	28
Total	75

^a In 27 out of 52 reviews no primary outcome measure was defined.

33,40,44,47,48,50,52–55,57], insufficient data reported in 6 reviews [9,14–16,21,53], too few included studies in 4 reviews [11,13,16,20], and other methodologic reasons in 2 reviews [44,51].

In 11 studies a qualitative data synthesis was performed, using five different methods [21,24,25,31,40,47,48,52–55]. The qualitative synthesis formulated by Van Tulder et al. was applied in seven reviews [21,25,31,41,52–54], and the adapted version was applied in two reviews [47,48]. In one review [55] two different qualitative syntheses were described [58,59], and in one review the authors formulated their own method [24].

The qualitative synthesis described by Smidt et al. [59] used the results of studies of high methodologic quality only, whereas the other qualitative syntheses also used the results of studies of low methodologic quality, which contributed to a low level of evidence (Table 2). Although four qualitative syntheses considered the consistency of findings, only those by Steultjens et al. [47,48] and Smidt et al. [59] defined consistency as a certain percentage of studies with positive findings (50 and 75%, respectively). Three qualitative syntheses took the power and/or statistical significance of findings into account. All qualitative syntheses required there to be at least two studies with positive findings to generate the highest level of evidence. Smidt [59] additionally required the findings to be of clinical relevance.

Steultjens et al. [47,48] applied a hierarchy to outcome measures. Thus, the outcome measures for level of activities and participation contributed to all levels of evidence, whereas those for level of impairments were considered as indicators of evidence and could only lead to “indicative findings” of evidence.

According to the qualitative synthesis described by Tugwell et al. [58], studies with noncontrolled designs can lead to a “silver” or “bronze” rating of evidence. In the qualitative synthesis of Steultjens et al. [47,48] such studies could lead to “indicative findings,” which was their lowest level of evidence. Only 2 of the 52 reviews included in our review included studies with a noncontrolled design. In one

of these [47], the overall conclusions were partly based on the results of studies with a pretest–posttest design.

4. Discussion

Our results strongly suggest that many of the systematic reviews of physiotherapy and occupational had similar methodologic problems, namely, clinical heterogeneity among interventions and outcome measures. Most reviews defined the primary outcome measures and categorized interventions in an attempt to deal with the problem of multiple outcomes, and in some cases, a qualitative synthesis was applied.

Our results suggest that heterogeneity is a common problem in systematic reviews of occupational therapy and physiotherapy. Both allied health professions can provide a variety of interventions, and these interventions are not specific to either profession. Therefore, systematic reviews on the efficacy of these treatments need criteria for the inclusion and the categorization of index interventions. Only a minority of reviews explicitly stated criteria for categorization. Steultjens et al. [47,48] described a procedure by which four experienced occupational therapists categorized studies of occupational therapy interventions in an attempt to achieve consensus on whether interventions were part of the domain of occupational therapy or not. This categorization of index interventions diminishes the problem of clinical heterogeneity among interventions; however, clinical heterogeneity is still possible because interventions can differ in intensity and duration, and can be applied to different groups of patients. For this reason, many reviews did not pool data because of clinical heterogeneity. Guidelines are not available on how to assess clinical heterogeneity among interventions. In the Cochrane Reviewers' Handbook, clinical judgement is considered the tool to determine clinical heterogeneity [60], but procedures to establish heterogeneity are not provided. Recently, meta-regression was suggested as statistical tool to detect heterogeneous treatment effects [61]. We recommend using two or more clinical experts to select relevant studies: categorize index interventions, and assess clinical heterogeneity.

All of the reviews included in our study defined multiple outcomes. Most treatment goals in occupational therapy are related to activity [2,62], whereas in physiotherapy they are typically related to both body functions and activities of the ICF [63]. Furthermore, it is recognized that outcome measures on the dimensions activities and participating in trials on the efficacy of physiotherapy and occupational therapy are most relevant [4,64–66]. This makes it surprising that only one-third of the reviews used ICF-associated measures as primary outcome measures. In fact, in half of the Cochrane reviews no primary outcome measures were defined; in the other reviews, about three primary outcome measures were used. We recommend that future reviews restrict the number of outcome measures and define primary outcomes

Table 2

Elements of the five different qualitative syntheses used in Cochrane reviews on physiotherapy and occupational therapy

	Gross [24]	Van Tulder [76]	Steultjens [47,48]	Tugwell [58]	Smidt [59]
Methodologic quality	Yes	Yes	Yes	Yes	Yes
Statistically significance/power	No	No	Yes	Yes	Yes
Consistency of findings	Yes	Yes	Yes	No	Yes
N of studies	Yes	Yes	Yes	Yes	Yes
Clinical relevance	No	No	No	No	Yes
Type of outcome measures	No	No	Yes	No	No
Type of designs	RCT	RCT, CCT	RCT,CCT, OD	RCT, CCT, OD	RCT
Possible outcomes	Strong evidence	Strong evidence	Strong evidence	Platinum	Strong evidence
	Moderate evidence	Moderate evidence	Moderate evidence	Gold	Weak evidence
	Limited evidence	Limited evidence	Limited evidence	Silver	Strong evidence for no difference
	Conflicting evidence	Conflicting evidence	Indicative findings	Bronze	
	No evidence	No evidence	No or insufficient evidence		Insufficient evidence
	Evidence of adverse effects				

Abbreviations: RCT, randomized clinical trial; CCT, controlled clinical trial; OD, other than controlled design.

measures regarding physiotherapy and occupational therapy, to decrease the likelihood of heterogeneity among outcome measures.

A few reviews used predefined decision rules for the qualitative data synthesis if quantitative data synthesis was not possible. Although this approach is criticized because there is no consensus about valid decision rules [67], the use of a qualitative synthesis is important if quantitative synthesis is inappropriate because of clinical and statistical heterogeneity. Five different methods of qualitative syntheses were used in 11 studies. Qualitative syntheses are built on different combinations of different aspects, but it is not possible to weigh the results of studies with regard to factors such as the number of patients included. Instead, typically, a method of “vote counting” is applied by summing the number of studies with positive results. “Statistical significance of findings” was used to define positive findings in three qualitative syntheses [47,58,59]. In two studies “Consistency of findings” was defined as a minimum percentage of studies with statistically significant results [47,59]. Statements about how to define positive results and how to count the number of positive studies are essential aspects of a qualitative synthesis. Yet only two qualitative syntheses [47,48,59] incorporated both aspects but differed in the percentage of studies that needed to show statistically significant and consistent results (50 and 75%, respectively). An unequivocal definition based on an international consensus on how to summarize findings of individual studies in a qualitative synthesis is clearly needed.

Two qualitative syntheses defined a level of evidence on the basis of evidence obtained in studies with noncontrolled

designs (Steultjens [47,48], indicative findings; Tugwell [58], Bronze). Such designs can only lead to a low level of evidence. In fact, the relevance of such studies to systematic reviews can be questioned. So far, Steultjens et al. [47,48] are the only authors to have included studies with a noncontrolled design in their systematic reviews. Their findings added little to the conclusions of the reviews because data from randomized controlled trials were available for most types of intervention. Furthermore, the methodologic quality and results of those studies did not contribute substantially to the qualitative synthesis. There is some debate about the interpretation of the results of studies with a noncontrolled design. Some argue that knowledge derived from noncontrolled studies is as important as knowledge from controlled studies because meta-analyses for both designs yield rather similar results [68–72]. Others refute the validity of meta-analysis of findings from noncontrolled studies because of possible systematic bias [73–75]. We consider the results of noncontrolled studies to be of value but less than that of the results of randomized controlled studies. The inclusion of studies with a noncontrolled design in systematic reviews should be limited to those areas where interventions are rapidly evolving and randomized clinical trials are very rare. In these areas the results of such studies might stimulate further research with more valid designs.

In conclusion, clinical heterogeneity is a common problem in Cochrane reviews of physiotherapy and occupational therapy. Explicit procedures for the inclusion and categorization of interventions may reduce clinical heterogeneity and increase the reproducibility of systematic reviews. The use of only a few relevant outcome measures is recommended. A qualitative synthesis will increase the transparency

of conclusions if a quantitative synthesis is inappropriate; however, international consensus on a method of qualitative synthesis is currently lacking.

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Table 1a
Characteristics of included reviews on physical and occupational therapy

First author	Disease/patient category	Intervention (in title review)	N of included studies	N of distinguished index intervention categories	Criteria/ consensus procedure used for categorization of interventions?	Quantitative synthesis performed?	Qualitative synthesis performed?
Gross [24]	Neck disorders	Manipulation and mobilization	33	5	no/no	yes	yes ^a
Assendelft [6]	Low back pain	Manipulation	39	1	no/no	yes	no
Bonaiuti [7]	Osteoporosis in postmenopausal women	Exercise	18	3	no/no	yes	no
Bradley [8]	Bronchiectasis	Physical training	2	1	no/no	yes	no
Busch [12]	Fibromyalgia syndrome	Exercise	16	4	yes/no	yes	no
Fransen [19]	Osteoarthritis hip–knee	Exercise	19	1	no/no	yes	no
Gillespie [22]	Elderly people	Preventing falls	62	12	no/no	yes	no
Glasscoe [23]	Cystic fibrosis	Psychological interventions	8	4	yes/no	yes	no
Handoll [26]	Distal radial fractures	Rehabilitation	12	8	no/no	yes	no
Hay Smith [28]	Incontinence	Pelvic floor muscle training	43	6	yes/no	yes	no
Hayes [30]	Schizophrenic-related conditions	Cognitive rehabilitation	3	1	no/no	yes	no
Holloway [32]	Asthma	Breathing exercises	7	1	no/no	yes	no
Lacasse [34]	Chronic obstructive pulmonary disease	Pulmonary rehabilitation	23	1	no/no	yes	no
Latham [35]	Older people	Progressive resistance training	66	2	no/no	yes	no
Leng [36]	Intermittent claudication	Exercise	10	1	no/no	yes	no
McDonald [37]	Hip or knee replacement	Preoperative education	9	1	no/no	yes	no
Moseley [38]	Stroke	Treadmill training and bodyweight support	11	3	yes/no	yes	no
Nixon [39]	Adults with HIV/AIDS	Aerobic exercise	8	5	no/no	yes	no
Outpatient Service Trialists [41]	Stroke patients	Rehabilitation services at home	14	1	no/no	yes	no
Pollock [42]	Postural control and lower limb function	Physiotherapy treatment approaches	11	4	yes/yes	yes	no
Ram [43]	Asthma	Physical training	8	1	no/no	yes	no
Saunders [45]	Stroke patients	Physical fitness training	12	3	yes/no	yes	no
Schonstein [46]	Workers with back and neck pain	Work conditioning, hardening, functional restoration	18	3	yes/yes	yes	no
Thomsen [49]	Knee injuries	Physiotherapist-led programs	31	16	no/no	yes	no
Vickers [56]	Preterm/low birth weight infants	Massage for promoting growth	13	2	yes/no	yes	no
Verhagen [55]	Rheumatoid arthritis	Balneotherapy	6	2	no/no	no	yes ^b
Steultjens [47]	Rheumatoid arthritis	Occupational therapy	38	6	yes/yes	no	yes ^a
Steultjens [48]	Multiple sclerosis	Occupational therapy	3	2	no/yes	no	yes ^a
Furlan [21]	Low back pain	Massage	8	1	no/no	no	yes ^c
Guzman [25]	Chronic low back pain	Biopsychosocial rehab	10	3	no/no	no	yes ^c
Heintjes [31]	Patellofemoral pain syndrome	Exercise therapy	12	2	no/no	no	yes ^c
Ostelo [40]	Lumbar disc surgery	Rehabilitation	13	3	no/no	no	yes ^c
Van Tulder [53]	Nonspecific low back pain	Back schools	15	2	yes/no	no	yes ^c
Van Tulder [52]	Low back pain	Exercise therapy	39	3	no/no	no	yes ^c

(continued)

Table 1a (continued)

First author	Disease/patient category	Intervention (in title review)	N of included studies	N of distinguished index intervention categories	Criteria/ consensus procedure used for categorization of interventions?	Quantitative synthesis performed?	Qualitative synthesis performed?
Verhagen [54]	Upper extremity work-related disorders	Ergonomic and physiotherapeutic interventions	15	7	no/no	no	yes ^c
Bradley [9]	Cystic fibrosis	Physical training	6	1	no/no	no	no
Brosseau [10]	Tendinitis	Deep transverse friction	2	1	no/no	no	no
Brosseau [11]	Osteoarthritis	Intensity of exercise	1	2	no/no	no	no
Campbell [13]	Children	Preventing obesity	10	3	no/no	no	no
Dagfinrud [14]	Bechterew's disease	Physiotherapy interventions	3	1	yes/no	no	no
Deane [17]	Dysphagia in Parkinson's disease	Nonpharmacologic therapies	0	1	no/no	no	no
Deane [16]	Parkinson's disease	Occupational therapy	2	1	no/no	no	no
Deane[18]	Parkinson's disease	Physiotherapy: comparison of t echniques	7	1	no/no	no	no
Deane [15]	Parkinson's disease	Physiotherapy versus placebo	11	1	no/no	no	no
French [20]	Bronchiectasis	Nurse specialist care	1	1	no/no	no	no
Handoll [27]	Hip fracture surgery	Mobilization strategies	6	5	no/no	no	no
Hay Smith [29]	Urinary and faecal incontinence	Physical therapies	15	1	no/no	no	no
Hondras [33]	Asthma	Manual therapy	5	4	no/no	no	no
Wallace [44]	Urinary incontinence	Bladder training	5	2	no/no	no	no
Van den Ende [50]	Rheumatoid arthritis	Dynamic exercise therapy	6	1	no/no	no	no
Van der Schans [51]	Cystic fibrosis	Chest physiotherapy	6	1	no/no	no	no
Young [57]	Back pain in pregnancy	Interventions for preventing and treating	3	3	no/no	no	no

^a No reference.^b References to both Tugwell et al. [58] and Smidt et al. [59].^c Reference to van Tulder et al. [76].